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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,640	11/28/2001	Jianwu Dai	TSS-052CP	5695

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EXAMINER	
NAFF, DAVID M	

ART UNIT	PAPER NUMBER
1651	6

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/996,670	Dai et al
Examiner	**Group Art Unit**
Knight	1657

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on 11/28/01.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1-31 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-31 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3, 4, & 5 2/4/02

☒ Notice of Reference(s) Cited, PTO-892

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Interview Summary, PTO-413

☐ Notice of Informal Patent Application, PTO-152

☐ Other _____

Office Action Summary

Claims examined on the merits are 1-31 which are all claims in the application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are confusing and unclear by claims 1 and 22 requiring optional steps. Setting forth steps that do not have to be carrier out confuses the invention that is to be patentably limiting. The optional steps should be omitted and required only when intended to be carried out such as in a dependent claim.

In d of claim 1, "mechanically expressing" is uncertain as to meaning and scope since the specification fails to describe in sufficient detail a specific method of mechanically expressing to be certain as to when mechanically expressing is being performed within the scope to the claim.

In line a of claims 6 and 26, "combining said biopolymer scaffold material with scaffolds made from naturally occurring, man-made or self-degrading polymers" is uncertain as to meaning and scope since the specification fails to describe combining the biopolymer scaffold other scaffolds.

In line 2 of b of claims 6 and 26, and line 2 of claims 5 and 25, -- a -- should be inserted before "lesion" to be clear.

In line 2 of claims 6, 26 and claim 30, -- delivery -- should inserted after "complex" to be clear.

Claims 6 and 26, in a, are confusing by requiring a signaling complex or signaling molecules to be factors extracted from the tissue or a blood vessel since in claims 1 and 22 extracting the factors is optional and claims 1 and 22 do not require the factors to be extracted. These claims should be dependent on a claim that requires the factors to be extracted. Additionally, "and treated with sodium hydroxide" is confusing since this is a process step and is not comprised by the signaling complexes. It is suggested that "and" before "treated" be replaced with -- after said extracted factors have been --.

Claims 7-19 that are dependent on claim 5 are unclear as to how the uses required relate to applying the scaffold to a lesion or to damaged tissue to promote tissue regeneration in claim 5. Additionally, claims 7-21 are confusing and unclear by requiring a method of using and not reciting method steps that result in the use required.

Claim 21 is confusing by requiring a scaffold produced in claim 6 since claim 6 requires using a scaffold rather than producing a scaffold. Furthermore, requiring the scaffold of claim 6 to provide a spinal fusion device as in claim 21 is confusing since claim 6 requires the scaffold to be used as a cell, signaling complex or drug deliver device. It is uncertain how these devices can be used to provide a spinal fusion device.

In line 2 of claim 21, the abbreviation "BMP" should be replaced with the full name to be readily clear as to the material required. This also applies to the abbreviation "DHT" in f of claim 24.

In line 1 of b of claim 24, reciting "said tissue" is confusing since claim 22 on which claim 24 depends does not recite tissue. Claim 22 requires a blood vessel.

In line 2 of c of claim 24, the "1:1 concentration" being in parentheses makes unclear as to whether this concentration is to be patentably limiting. It is suggested that "(1:1 concentration)" in line 2 be deleted, and in line 1 of c before "chloroform" insert -- 1:1 concentration of --.

In line 3 of a of claim 26, "said signaling molecules" is confusing since signaling molecules have not been previously required. Line 2 of claim 26 requires a "signaling complex".

In line 1 of claims 27 and 28, "chosen" should be changed to -- selected -- to set forth a proper Markush group.

Claim 30 is unclear by requiring a cell, signaling complex or drug deliver device as in claim 25 since claim 25 is a method of using a scaffold and does not require producing a device as required by claim 30.

Claim 31 is confusing by reciting "said signaling complexes" since claim 25 on which claim 31 depends does not require signaling complexes.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art

> are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brendel et al (4,801,299) in view of Bell et al (6,179,872 B1).

The claims are drawn to a method of producing a biopolymer scaffold by harvesting tissue, inactivating infective agents, mechanically expressing undesirable components, delipidizing and washing, and to methods of using the scaffold.

Brendel et al disclose (col 2, line 48 to col 3, line 58) producing an extracellular matrix for implanting by treating tissue to remove cellular membranes, nucleic acids, lipids and cytoplasmic components by treating tissue with detergents, washing, treating with ethylene oxide or irradiation to sterilize, and lyophilizing. Crosslinking may also be performed.

Bell et al disclose (col 1, lines 46-57) producing extracellular matrix particulates from tissue for use in preparing a biopolymer matt

for repairing tissue. Tissue is processed by grinding, washing and sieving to remove cytoplasmic and nuclear components , and the resultant extracellular matrix is freeze-dried.

It would have been obvious to use grinding of tissue in removing cytoplasmic components from tissue in the process of Brendel et al for producing an extracellular matrix as suggested by Bell et al using grinding for removing cytoplasmic components to produce an extracellular matrix. Grinding would have been expected to disrupt the tissue and provide better access for the detergents of Brendel et al to the interior of tissue cells for carrying out the desired removal of cellular membranes, nucleic acids, lipids and cytoplasmic components. Grinding is mechanically expressing. Additionally, grinding and using the detergents of Brendel et al will inherently inactivate infective agents and delipidize. The conditions of dependent claims would have been matters of obvious choice in view of the disclosures of the references.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-31 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22-46 of copending Application No. 09/871,518. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims encompass the methods of producing a biopolymer scaffold claimed by the copending application, and would have been obvious therefrom.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is (703) 308-0520. The examiner can normally be reached on Monday-Thursday and every other Friday from about 8:30 AM to about 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, a message can be left on voice mail.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached at telephone number (703) 308-4743.

The fax phone number is (703) 872-9306 before final rejection or (703) 872-9307 after final rejection.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 1651

DMN
3/20/03